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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,330	12/27/2001	Orville G. Kolterman	030639.0027.US1	2741
44638	7590	08/26/2004	EXAMINER	
ARNOLD & PORTER LLP (18528) 555 TWELFTH ST, NW WASHINGTON, DC 20004			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,330

Applicant(s)

KOLTERMAN ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-125 is/are pending in the application.
- 4a) Of the above claim(s) 43-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims.

Claims 43-125 are pending.

Applicants' amendment Applicants' amendment filed 20 July 2004, which cancels claims 1-42 and adds claims 84-125 has been entered.

The following Office Action is applicable to the pending claims 84-125. Note that claims 43-83 were withdrawn from further consideration by Examiner (see the Office action mailed 19 May 2004).

Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 84-125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 84 recites "1.0% w/v"; the recitation is not apparent as to what the "w/v" refers. If it refers to a unit for "10%", it should be embraced in parentheses; or, it renders the claim indefinite. Claim 84 recites "about 0.005% to about 0.4% (w/v)" wherein "0.005%" lacks unit (e.g., 0.005% (w/v)); such the recitation renders the claim indefinite because, without reciting the unit, 0.005% ambiguously refers to having unit of w/w, or v/v, or w/v, or no unit at all. See also claim 86, 91, 93, 105 and 117-118. Also, claim 84 is indefinite in "any combination thereof" because it is ambiguous regarding whether or

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not all the preservatives (recited in a Markush group) are formulated in the formulation or only any two different preservative molecules are formulated. See also claim 105.

Further, claim 84 is indefinite because of the open Markush group which is ended up with the phrase “and any combination thereof”; Markush group requires close language. Note that “and any combination thereof” extends the claim to include *at least more than one* selected preservative. The dependent claims are also rejected.

Claim 87 recites an open Markush group because the group is ended up with the phrase “*and any combination thereof*”; Markush group requires close language. How many possibilities are derived from “any combination thereof? does the claimed buffer encompass acetate buffer, glutamate buffer, citrate buffer and/or phosphate buffer? See also claims 94-95, 113 and 119-120.

Claim 93 recites “*or a combination thereof*”; the recitation renders the claim indefinite because it is unclear as to whether or not the claimed iso-osmolarity modifier is a mix (combination) of sorbitol or/and mannitol or/and inositol or/and glycerol or/and xylitol or/and polyethylene glycols.

Provisional Rejection - Obviousness Type Double Patenting

Claim 105 of this application conflicts with claims 1 of Application No. 10157224. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either

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cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 105 is provisionally rejected under the judicially created doctrine of double patenting over claim 1 of Application No. 10157224. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

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Claim 1 of Application 10157224 discloses a pharmaceutical composition comprising exendin 4 in a release formulation; the specification sets forth that the invention includes liquid formulations of the exendin which is mixed with a buffer (preferably an acetate buffer), an iso-osmolality modifier (preferably mannitol), and optionally containing a preservative (preferably m-cresol) (see [0201]), which has concentration of 0.005 to 1.0% (w/v), selected from the group consisting of m-cresol, benzyl alcohol, methyl ethyl, propyl and butyl parabens and phenol (see [0203]). Thus, 10157224 claim 1 is an obvious variation of the subject matter set forth in claim 105 of the current application.

Therefore, the instant application and Application No. 10157224 claims are obvious variation, and they are not patentably distinct from each other.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

swl

Samuel Wei Liu, Ph.D.

Art Unit 1653, Examiner

May 5, 2004

Karen Cochrane Carlson Ph.D.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER